KENTUCKY BOARD OF PHARMACY

STATE OFFICE BUILDING ANNEX, STE 300
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Revised 2/2016

NONSTERILE COMPOUNDING

Pharmacy:_____ **Permit:**_____ **Date of Inspection:**_____

Street Address: _____ **City**:_____ **State:**_____

COMPOUNDING PERSONNEL

NAME	PHARMACIST	TECHNICIAN
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

COMPOUNDING AMOUNTS

TYPE	% or total per day/week/month	Hazardous % or per day/week/month	Controlled Substances % or per day/week/month	Veterinary %/per day
TOTAL				
SIMPLE				
MODERATE				
COMPLEX				
ANTICIPATORY				
OFFICE USE				

PRODUCTS INSPECTED

NAME/STRENGTH	QUANTITY	LABELED	BUD
1.			
2.			
3.			
4.			
5.			

LIST OF STATES

STATE	PERMITTED IN	SHIP TO	INSPECTED BY
1.			
2.			
3.			
4.			
5.			

Inspected by FDA, if yes, please list date and results of inspection:

Accredited by an organization, if yes, please list and date of last survey:

Inspected by another state or entity, if yes, please list date and state/entity:

Are CNSPs significantly different from commercially available products that are justified by a documented medical need of the individual patient as determined by the prescriber; if yes, please list CNSP:

Types of CNSPs compounded, capsules, tablets, liquids, creams, gels, ointments, patches, pellets, compounding with crushed tablets, etc:

Is there a sales force to promote compounding, if yes, is it contract or employees:

Familiar with USP Chapter 800:

Black: Required **Red: Best Practice**

POLICIES AND PROCEDURES	COMPLIANT	NON COMPLIANT	N/A	NOT INSEPCTED
Description of test or examinations conducted on CNSP to ensure uniformity and integrity. [QUALITY CONTROL – Compounding Controls]				
Recommended all significant procedures performed in the compounding area should be covered by P&Ps. [COMPOUNDING DOCUMENTATION – Standard Operating Procedures]				
Recommended P&P for facility, equipment, personnel, preparation, packaging and storage of NSCP to ensure accountability, accuracy, quality, safety, and uniformity in compounding. [COMPOUNDING DOCUMENTATION – Standard Operating Procedures]				
COMMENTS:				

TRAINING [Training]	COMPLIANT	NON COMPLIANT	N/A	NOT INSPECTED
Documented training of all technician(s) performing nonsterile compounding, signed by Trainer.				
Documented training of all pharmacist(s) performing and/or supervising nonsterile compounding, signed by Trainer.				
Training is appropriate to category of compounding, simple, moderate and/or complex.				
Read USP 795 and familiarity with USP.				
Familiar with all compounding procedures, including facility, equipment, personnel, actual compounding, evaluation, packaging, storage, and dispensing.				
Trained on hazardous drugs procedures prior to use, including waste removal and cleaning storage and prep areas. [Training and COMPOUNDING FACILITIES]				
Trainer demonstration of each procedure employee will be performing.				
Employee observed demonstration of each procedure employee will be performing.				
Training is ongoing.				
Compounder continually monitoring the work of the employee, ensuring accuracy.				
COMMENTS:				

COMPONENTS [COMPONENT SELECTION, HANDLING AND STORAGE]	COMPLIANT	NON COMPLIANT	N/A	NOT INSPECTED
Consideration of excipients and effect of manipulating manufactured product on therapeutic appropriateness and stability of NSCP.				
APIs purchased from an FDA-registered facility, if cannot may use a reliable source as determined by compounder.				
Components USP, NF or FCC substance, when available.				
API is not USP/NP, identity, purity and safety established by professional judgment, reliability of source, testing.				
COAs available.				
Components stored to USP or manufacturer specifications in a clean area off the floor.				

COMPONENTS continued [COMPONENT SELECTION, HANDLING AND STORAGE]	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Components stored in appropriate temperature and humidity conditions: 1. Controlled room temperature (68 to 77 F or 20 to 25 C) 2. Controlled refrigerator temperature (36 to 46 F or 2 to 8 C) 3. Controlled freezer temperature (-13 to 14 F or -25 to -10C) 4. Humidity (Recommended 35 to 60%)				
Hazardous components stored separately.				
Components expiration date: Manufacturer assigned expiration date.				
Facility assigned expiration date: receipt date on package and not greater than 3 years from date of receiving.				
If transfer APIs into different containers, label shall bear: 1. Component name 2. Original supplier 3. Lot number 4. Transfer date 5. Expiration date				
Transfer container integrity shall be equivalent to or better than the original container.				
Bulk component containers OSHA labeled. [RESPONSIBILITES OF THE COMPOUNDER: General Principles of Compounding]				
SDSs available for all components. [RESPONSIBILITIES OF THE COMPOUNDER: General Principles of Compounding]				
Components not listed on FDA's withdrawn list. [COMPOUNDING PROCESS]				
COMMENTS:				

EQUIPMENT [COMPOUNDIG EQUIPMENT]	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Appropriate for compound.				
Contact components: not reactive, additive, or sorptive.				
Equipment stored to prevent contamination.				
Equipment routinely inspected.				
Equipment routinely calibrated.				
Equipment routinely checked to ensure proper performance.				
Inspected immediately prior to use.				
Appropriately cleaned after use, recommended to rinse equipment and utensils with purified water [COMPOUNDING FACILITY].				
Recommended certification of powder containment hood.				
Designated equipment for hazardous drugs or antibiotics or have procedures for cleaning shared equipment. [COMPOUNDING EQUIPMENT]				

COMMENTS:

COMPOUNDING FACILITY [COMPOUNDING FACILITES]	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Compounding area restricted to authorized personnel. [RESPONSIBILITES OF THE COMPOUNDER: General Principles of Compounding]				
Adequate space recommended that is well lighted.				
Space is clean, orderly and sanitary.				
Nonsterile compounding area is separate and distinct from sterile compounding area.				
Washing facilities easily accessible to the compound area with hot and cold water and soap/detergent to wash with.				
Use air-drier or single-use towels.				
Waste is disposed of in sanitary and timely manner.				
HVAC controlled to prevent decomposition and contamination.				
Appropriate temperature: recommended monitoring.				
Appropriate humidity: recommended monitoring.				
Hazardous waste disposal.				

COMMENTS:

COMPOUNDING PROCESS [COMPOUNDING PROCESS]	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Personnel maintain good hand hygiene.				
Personnel wear clean clothing.				
Appropriate PPE for compound: gloves, shoe covers, hair covers, facemasks, etc.				
One preparation at a time compounded in a specific area.				
Critical process verified, including but not limited to weighing, measuring and mixing.				
Pharmacist reviewing each procedure in compounding process to include: 1. Assurance of correct ingredients 2. Assurance of correct calculations 3. Accurate measurements 4. Appropriate conditions 5. Professional judgment [QUALITY CONTROL]				
Master Formulation Record followed.				
Compounding Record created.				
Purified water used in preparations requiring water. [COMPOUNDING FACILITIES]				

COMPOUNDING PROCESS continued [COMPOUNDING PROCESS]	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Dose, safety, and intended use of the NSCP has been evaluated for suitability of: 1. Chemical and physical properties of the components 2. Dosage form 3. Therapeutic appropriateness and route of administration 4. Legal limitations, if any				
Final preparation assessed appropriately for weight, clarity, odor, color, consistency, pH, as appropriate				
Assigned appropriate BUD for nonaqueous NSCPs: earliest expiration date of component used or 6 months, at controlled room temperature, from date of compounding, whichever is less. [BUD by Type of Formulation]				
Assigned appropriate BUD for aqueous oral NSCPs: earliest expiration date of component used or 14 days at controlled cold temperature, from date of compounding, whichever is less. [BUD by Type of Formulation]				
Assigned appropriate BUD for aqueous topical/dermal/semi-solid NSCPs: earliest expiration date of component used or 30 days, at controlled room temperature, from date of compounding, whichever is less. [BUD by Type of Formulation]				
If extend BUD, documented stability data for specific drug and preparation (testing). [General Guidelines for Assigning Beyond-Use Dates]				
Recommended potency testing performed.				
Compounding Record reviewed by pharmacist.				
Preparation labeled with BUD.				
Preparation labeled with storage instructions.				
Recommended preparation labeled with statement, “this is a compounded preparation.”				
Finished product dispensed in suitable container.				
COMMENTS:				

COMPOUNDING DOCUMENTATION [COMPOUNDING DOCUMENTATION]	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Master Formulation: 1. Preparation name, strength, dosage form 2. Required calculations 3. Ingredients description and quantity 4. Compatibility and stability information, including reference when available 5. Necessary equipment 6. Mixing instructions: with the following recommended to be documented: A. Order B. Temperature C. Environment D. Duration E. Factors pertinent to replication 7. Labeling information: A. Generic name and quantity/concentrations B. Assigned BUD C. Storage conditions D. Prescription or control number 8. Dispensing container 9. Packaging and storage requirements 10. Description of final preparation 11. Quality control procedures and expected results				
Compounding Record: 1. Assigned name, strength, and dosage of preparation 2. Master Formulation Record reference 3. Names and quantities of all components 4. Component sources, lot numbers and expiration dates 5. Total quantity compounded 6. Name of person compounding 7. Name of person performing quality checks 8. Name of pharmacist verifying preparation 9. Date of preparation 10. Assigned prescription number or control number 11. Assigned BUD 12. Duplicate label 13. Description of final preparation 14. Results of quality check 15. Quality control issues documented 16. Deviations from procedures documented 17. Adverse reactions or preparations problems documented				
Quality control issues documented.				
Deviations from procedures documented.				
Adverse reactions or preparation problems documented.				
Adequate procedures to investigate and correct problems in compounding, testing, or the preparation itself. [RESPONSIBILITIES OF THE COMPOUNDER: General Principles of Compounding]				

COMMENTS:

COUNSELING [PATIENT COUNSELING]	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Counsel about proper use, storage, handling and disposal of NSCP.				
Instruct patient/caregiver to report adverse reactions.				
Instruct patient/caregiver to report physical changes in NSCP.				
Documented investigation and corrective action of reported problem with NSCP.				

COMMENTS:

ANIMAL [COMPOUNDING FOR ANIMAL PATIENTS]	**COMPLIANT**	**NON COMPLIANT**	**N/A**	**NOT INSPECTED**
Determine type of animal: companion, performance, food.				
If food-producing animal, must include withdrawal time (WDT) on label of NSCP.				
Knowledge of drug regulation and disposition in animals.				
Knowledge of species' limitation when metabolizing drugs that could result in toxicity.				
Use formulation specifically for animals.				
If animal formulation unavailable, pharmacist conducts literature search of components to determine toxicity to animal.				

COMMENTS:

ADDITIONAL COMMENTS: